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PRICE *et al.*

TECH CENTER 1600/2900 Appl. No. 09/693,949

Remarks

Reconsideration of this Application is respectfully requested.

Upon entry of the foregoing amendment, claims 1-13, 18-21, 26, 29-32 and 34-40 are pending in the application, with claims 1, 2, 6, 7 and 26 being the independent claims. Claim 33 is sought to be cancelled without prejudice to or disclaimer of the subject matter therein.

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

I. Examiner Interview – Finality of Office Action

Applicants thank the Examiner for the Examiner Interview conducted on September 3, 2002 in which the finality of the Office Action dated July 15, 2002 was discussed. As indicated in the Interview Summary (Paper No. 15), the finality of the Office Action has been withdrawn. Accordingly, this Reply is being filed under 37 C.F.R. § 1.111.

II. Claim Objection

Claim 33 was objected to under 37 C.F.R. § 1.75(c), as allegedly being of improper dependent form for failing to further limit the subject matter of a previous claim. *See* Paper No. 14, page 2. Applicants note that claim 33 has been cancelled, thereby obviating this objection.

III. Double Patenting

The Examiner has maintained the rejection of claims 1-13, 18-21, 26 and 29-38 under the judicially-created doctrine of obviousness-type double patenting. *See* Paper No. 14, Page 3. Applicants respectfully request that this rejection be held in abeyance until the remaining outstanding issues in this application are resolved.

IV. Claim Rejections Under 35 U.S.C. § 102

Claims 1, 2, 12, 13, 26 and 33-38 were rejected under 35 U.S.C. § 102(b) as allegedly being anticipated by DIFCO manual in light of *Dyas et al., Photochemistry* 35:655-660 (1994) (hereinafter "Dyas"). *See* Paper No. 14, page 3. Applicants respectfully traverse this rejection.

According to the Examiner:

The DIFCO manual teaches potato based culture media (see page 690-691). This media would contain peptides and lipids. The reference does not specifically teach using this cell media to culture animal cells; however, since the composition taught by the reference is the same as the claimed composition, the reference composition would inherently have to [have] the same cell culture ability if applicant's invention functions as claimed.

See Paper No. 14, page 3. Applicants respectfully disagree with the Examiner's conclusion. Under 35 USC § 102, a claim can only be anticipated if every element in the claim is expressly or inherently disclosed in a single prior art reference. *See Kalman v. Kimberly Clark Corp.*, 713 F.2d 760, 771 (Fed. Cir. 1983), *cert. denied*, 465 U.S. 1026 (1984). Since the DIFCO manual does not teach or suggest all of the elements of Applicants' claims, the DIFCO manual cannot and does not anticipate Applicants' claims.

Applicants' claims are directed to cell culture media comprising at least one non-animal or plant-derived peptide. Importantly, Applicants claims specify that "said medium is capable of supporting the cultivation of an animal cell *in vitro*." Those of ordinary skill in the art would clearly recognize that there are certain aspects of cell culture media that render such media capable of supporting the cultivation of an animal cell and that these aspects are lacking in the compositions set forth in the DIFCO manual. The DIFCO manual describes a "Potato Dextrose Agar" and a "Potato Dextrose Broth," both of which are used to culture yeasts and molds. There is no suggestion that the DIFCO compositions would be capable of supporting the cultivation of an *animal* cell. In fact, it is well known in the art that media that support the cultivation of animal cells contain more ingredients, and are much more complicated in terms of the relative proportions of their constituent ingredients, as compared to media used for the growth of yeasts and molds. *See, e.g.*, specification at pages 11-19 (demonstrating the types of considerations that go into the formulation of an animal culture medium), *see also* Allen R. Liss, *Methods for Preparation of Media, Supplements and Substrate for Serum-Free Animal Cell Culture* (cited and incorporated by reference in the specification at page 10, lines 13-15.) The compositions in the DIFCO manual contain only (1) infusion from potatoes, (2) dextrose, and/or (3) agar. Applicants submit that media containing these ingredients would not support the growth of animal cells. Thus, the DIFCO manual does not teach or suggest all of the elements of Applicants' claims.

The Examiner has acknowledged that the DIFCO manual "does not specifically teach using this cell media to culture animal cells." The Examiner, however, stated that "since the composition taught by the reference is the same as the claimed composition, the reference compositions would inherently have to [have] the same cell culture ability if applicant's

invention functions as claimed." As noted above, the compositions set forth in the DIFCO manual are not capable of supporting the cultivation of an animal cell *in vitro* and therefore are not "the same as the claimed composition." Moreover, in order to properly base an anticipation rejection on the doctrine of inherency, the allegedly inherent element must *necessarily* be present in the cited reference. *See In re Schreiber*, 128 F.3d 1473, 1477, 44 USPQ2d 1429, 1431 (Fed. Cir. 1997). Inherency, may not be established by probabilities or possibilities; the mere fact that a certain thing may result from a given set of circumstances is not sufficient to establish inherency. *See id.* *See also Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Int'f 1990 ("In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.") In this instance, the Examiner has not demonstrated that the compositions in the DIFCO manual *necessarily* are capable of supporting the cultivation of an animal cell *in vitro*. Therefore, the rejection of Applicants' claims cannot be based on an inherency argument.

Since the DIFCO manual does not teach or suggest all of the elements of any of Applicants' claims, Applicants respectfully request that the rejection of claims 1, 2, 12, 13, 26 and 33-38 under 35 U.S.C. § 102(b) be reconsidered and withdrawn.

V. Claim Rejections Under 35 U.S.C. § 103

A. DIFCO Manual in light of Dyas in view of Gibco Catalogue

Claims 1-5, 8-13, 26 and 29-38 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over the DIFCO manual in light of Dyas, in view of Gibco BRL Life Technologies Catalogue and Reference Guide (hereinafter "Gibco Catalogue"). *See* Paper No. 14, page 4. Applicants respectfully traverse this rejection.

The Examiner, in supporting this rejection, has relied on the DIFCO manual for teaching a culture medium from potato. *See* Paper No. 14, page 4. The Gibco Catalogue is relied upon as an indication that lipoic acid and myristate can be added to the culture medium disclosed in the DIFCO manual. In view of these two references, the Examiner concluded that "an artisan of ordinary skill would have been motivated to add lipoic acid and myristate to the culture medium of the DIFCO manual." *See* Paper No. 14, page 4.

As discussed above, the compositions disclosed in the DIFCO manual are used to culture only yeasts and molds; they would be ineffective at supporting the cultivation of an animal cell. Thus, the addition of lipoic acid and myristate to the compositions disclosed in the DIFCO manual would not yield a culture media that falls within the scope of Applicants' claims. That is, the addition of lipoic acid and myristate to the compositions disclosed in the DIFCO manual would not produce a cell culture medium capable of supporting the cultivation of an animal cell *in vitro*. *See* discussion above.

Moreover, in order to establish a *prima facie* case of obviousness, there must be some suggestion, teaching or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or

to combine reference teachings. *See In re Rouffet*, 149 F.3d 1350, 1357, 47 USPQ2d 1453, 1457-58 (Fed. Cir. 1998). Evidence of a suggestion, teaching, or motivation to combine references must be "clear and particular." *See In re Dembiczak*, 175 F.3d 994, 999, 50 USPQ2d 1614, 1617 (Fed. Cir. 1999). "Broad conclusory statements regarding the teaching of multiple references, standing alone, are not 'evidence.'" *Dembiczak*, 175 F.3d at 999, 50 USPQ2d at 1617.

Here, the Examiner has merely stated that a skilled artisan would "reasonably assume" that lipoic acid and myristate could "beneficially be added" to the DIFCO compositions. The Examiner, however, has not pointed to anything in particular to support these assertions. As articulated by the Federal Circuit, "[o]bviousness cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination." *ACS Hosp. Sys., Inc. v. Montefiore Hosp.*, 732 F.2d 1572, 1577, 221USPQ 929, 933 (Fed. Cir. 1984). Since the Examiner has not shown that a persons of ordinary skill in the art would have been motivated to combine the disclosures of the DIFCO manual and the Gibco Catalogue, a *prima facie* case of obviousness has not been established.

Since there is no motivation to combine the disclosures of the DIFCO manual and the Gibco Catalogue, and since the combination, in any event, would not have resulted in a medium that falls within the scope of Applicants' claims, Applicants respectfully request that this rejection of claims 1-5, 8-13, 26 and 29-38 under 35 U.S.C. § 103(a) be reconsidered and withdrawn.

B. U.S. Patent No. 5,122,469 in view of Dyas and Gibco Catalogue

Claims 1-13, 18-21, 26 and 29-38 were rejected under 35 U.S.C. § 103(a) as allegedly being unpatentable over U.S. Patent No. 5,122,469 (hereinafter "the '469 patent") in view of Dyas and the Gibco Catalogue. *See* Paper No. 14, page 4. Applicants respectfully traverse this rejection.

As stated above, an obviousness rejection cannot be properly made unless there is a "clear and particular" motivation, either in the cited references or in the art generally, suggesting to one of ordinary skill in the art to combine or modify the reference disclosures. *See Rouffet*, 149 F.3d at 1357, 47 USPQ2d at 1457-58; *Dembiczak*, 175 F.3d at 999, 50 USPQ2d at 1617 (Fed. Cir. 1999). Here, the Examiner has simply made three unsupported conclusory statements regarding the supposed motivation for one skilled in the art to combine or modify the reference disclosures. As discussed below, these statements are legally insufficient to establish a *prima facie* case of obviousness under 35 U.S.C. § 103.

First, regarding the addition of peptone, lipids and lipoic acid to culture media, the Examiner acknowledged that the '469 patent does not teach a single culture medium containing all three of these ingredients. *See* Paper No. 14, page 5. In an attempt to show motivation to combine the ingredients, however, the Examiner stated: "since all of the ingredients can be used for the *same purpose*, an artisan of ordinary skill in the art would reasonably expect that a combination of the ingredients would form a media capable of culturing animal cells." *See* Paper No. 14, page 5 (emphasis added). This is simply an unsupported conclusion. The Examiner does not state what the so called "same purpose" is for these ingredients. Nor does the Examiner point to anything specific that indicates or suggests that the ingredients can be used for the so called "same purpose." In fact,

Applicants submit that these ingredients all support different metabolic processes in animal cells (*e.g.*, lipids contribute to cell membrane integrity and participate in hormone synthesis while peptone supplies amino acids for the synthesis of enzymes and other proteins in the cell). Thus, it is incorrect to state that they can be used for the "same purpose." In addition, the Examiner's statement as to what one of ordinary skill in the art would "reasonably expect" is not supported by any particular evidence and, by itself, does not constitute a legally sufficient showing of motivation to modify or combine the reference disclosure. *See Dembiczak*, 175 F.3d at 999, 50 USPQ2d at 1617.

Second, the Examiner noted that the '469 patent does not teach that potato can be used as a source of lipids and peptides. The Examiner concluded, however, that since it is "known in the art that potatoes contain these substances. . . an artisan of ordinary skill would reasonably expect that potatoes could be used as a source of the lipids and peptides." *See* Paper No. 14, page 5. The simple fact that potatoes contain lipids and peptides does not, in and of itself, provide sufficient motivation, under § 103, for a skilled artisan to use potatoes as a lipid and peptide source; *i.e.*, the mere fact that a reference disclosure *may* be modified does not mean that a skilled artisan would be motivated to actually make the modification. *See In re Mills*, 916 F.2d 680,682, 16 U.S.P.Q.2d 1430, 1432 (Fed. Cir. 1992). Applicants also emphasize that, under applicable Federal Circuit case law, the motivation to modify a reference disclosure, in the context of an obviousness rejection, must be "clear and particular." *See Dembiczak*, 175 F.3d at 999, 50 USPQ2d at 1617. The Examiner has simply relied upon the Examiner's own unsupported belief as to what one of ordinary skill in the art would "reasonably expect" without providing evidence or pointing to anything specific that supports this contention.

Third, the Examiner acknowledged that the '469 patent does not teach the addition of myristate to culture media. *See* Paper No. 14, page 5. Nevertheless, the Examiner asserted that "[t]he Gibco catalog show[s] that myristate (see page 4-63) is an ingredient that can be added to a culture medium." *See* Paper No. 14, page 5. Based solely on the interpretation that the Gibco Catalogue indicates that myristate can be added to a culture medium, the Examiner concluded that "a person of ordinary skill in the art would reasonably assume that this ingredient could beneficially be added to the culture medium taught by the US '469." *See* Paper No. 14, page 5. Again, Applicants respectfully assert that the Examiner has not provided legally sufficient evidence of a motivation to combine the reference disclosures. Rather, the Examiner has simply made an unsupported statement regarding what one of ordinary skill in the art would "reasonably assume."

What one skilled in the art may or may not "reasonably expect," or "reasonably assume," by itself, cannot form the basis of a proper obviousness rejection. There must be a clear and particular showing of a motivation to modify or combine references. Since no such evidence has been put forth in this instance, a *prima facie* case of obviousness has not been established. Applicants therefore respectfully request that this rejection of claims 1-13, 18-21, 26 and 29-38 under 35 U.S.C. § 103(a) be reconsidered and withdrawn.



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Conclusion

All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn. Applicants believe that a full and complete reply has been made to the outstanding Office Action and that, *e.g.*, upon submission of a Terminal Disclaimer, the present application will be in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

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Version with markings to show changes made

Claim 33 is sought to be cancelled.

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